

II. Remarks

A. Introduction

Reconsideration and allowance of the present application are respectfully requested.

Claims 1, 2, 4, 5, 10-12, 17-23, 25, 26, 28, 30-36, 38, 39, and 42-45 are pending in the present application. Claims 1, 25, 30 and 39 are independent. Claims 1, 10-12, 25, 30, 32-36, 38, and 39 are amended. Claims 3, 37, 40 and 41 are cancelled in this amendment. Claim 45 is added. No new matter has been introduced.

Applicant acknowledges that the previous rejection under 35 U.S.C. § 112 for lacking enablement has been withdrawn.

B. Claim Rejections under 35 U.S.C. § 112

Claims 1-5, 10-12, 16-23, 25, 26, 28, and 30-39 stand rejected under 35 U.S.C. § 112, second paragraph, for being indefinite. The Office Action states “it is unclear if said first layer and adhesive are also transparent” and that there is confusion between Claims 1 and 39. (*See* Office Action, page 3). Applicant disagrees that there is any confusion between Claims 1 and 39. As stated in the application, the first adhesive layer may be transparent. (*See* para. 27, page 10). Furthermore, based on the amendments to the claims, this rejection should be reconsidered and withdrawn.

In response to Applicant’s previous arguments filed on February 18, 2010, the Office Action has misconstrued Applicant’s arguments. The Office Action states that “Applicant argues that one of ordinary skill in the art would readily understand all issues dealing with the transparency of said patch.” (*See* Office Action, page 10). Applicant did not make this statement. Applicant did state that the “standard for determining definiteness of a claim is based on whether a person of ordinary skill would understand with a reasonable degree of clarity.” (*See* Response Feb. 18, 2010, page 7). Applicant requests that the statement in the outstanding Office Action be withdrawn as improper.

C. Claim Rejections under 35 U.S.C. § 102(b)

Independent Claim 1 stands rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 6,241,998 to Muchin (hereinafter “Muchin”) for the reasons set forth in the Office Action. Applicant respectfully traverses this rejection in view of the following remarks.

1. Muchin Fails to Teach UVA and UVB Agents or a UPF of at least 15

Independent Claim 1, as amended, recites a “patch applied to skin for reducing exposure to ultraviolet (UV) radiation” comprising “a second layer adjacent to the first layer comprising a material; and one or more UVA (320-400 nm) radiation blocking agent and one or more UVB (280-320 nm) radiation blocking agents” and “the patch comprises a UV protection factor (UPF) of at least 15.” Claim 1 has been amended to recite the features of dependent Claim 37. Muchin does not disclose a patch which has at least one UVA radiation blocking agent and at least one UVB radiation blocking agent. In addition, Muchin does not disclose a patch which has a UPF of at least 15. Therefore, for this additional reason, Muchin cannot anticipate Claim 1 and this rejection must be withdrawn.

2. Muchin Fails to Teach a Pad (Second Layer) that Contains UVA and UVB Agents.

Independent Claim 1, as amended, recites a “patch applied to skin for reducing exposure to ultraviolet (UV) radiation” comprising “a second layer adjacent to the first layer comprising a material; and one or more UVA (320-400 nm) radiation blocking agent and one or more UVB (280-320 nm) radiation blocking agents.” It is clear that the second layer comprises one or more UVA and UVB radiation blocking agents. The adhesive layer is the first layer in the recited claim, not the second layer. Claim 1 does not recite that the adhesive layer comprises UV radiation blocking agents. The Office Action states that “Muchin teaches zinc oxide in said adhesive layer.” (*See* Office Action, page 20). Muchin clearly states that “**polymeric adhesive composition** can further contain optional ingredients which are generally incorporated into cosmetic preparations” including “UV absorbers.” (*See* Muchin, Col. 5, lines 48-50 and Col. 6, line 1; emphasis added). There is no teaching in Muchin that the pad, e.g., second layer as recited in Claim 1, contains one or more UV radiation blocking agents. In direct contrast, the adhesive layer of Muchin, e.g., first layer as recited in Claim 1, contains one or more UV radiation blocking agents. Therefore, Muchin cannot anticipate Claim 1 and this rejection must be withdrawn.

The Office Action has grossly misconstrued Applicant's previously arguments by stating that "Applicant also argues that Muchin does not teach UV agents and does not teach an adhesive layer with UV blocking agents." (*See* Office Action, page 20). In the previous response, Applicant argued that "Muchin fails to disclose a second layer adjacent to the first layer comprising one or more UV blocking agents as claimed." (*See* Response Feb. 18, 2010, page 12). Applicant recited the claim language of Claim 1. "Adjacent to the first layer" defines the location of the second layer and the word comprising clearly modifies the second layer not the first layer. Therefore, this rejection must be withdrawn as improperly based on incorrect understanding of the claims and arguments.

D. Claim Rejections under 35 U.S.C. § 103(a)

1. Muchin Fails to Suggest the Recited Claimed Features

Independent Claims 1, 25, 30, and 39, as well as dependent Claims 4, 5, 11, 12, 16-20, 22, 23, 28 and 31-38 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Muchin. Applicant traverses the rejection based on the following arguments.

The Office Action states that Muchin allegedly teaches an "adhesive layer, a UV agent and a transparent backing layer." (*See* Office Action, page 3). The Office Action also admits that Muchin fails to teach all "limitations are combined into a single composition." (*See* Office Action, page 5). To remedy this deficiency of Muchin, the Office Action states that one would merely "select each component and combine them as instantly claimed because Muchin suggests that the instant components can be combined or mixed together." (*See* Office Action, page 6). Applicant disagrees. It is improper to merely identify various elements identified separately in a reference, because doing so "would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention." (*See In re Rouffet*, 149 F.3d 1350, 1357-58 (Fed. Cir. 1998)). The Office Action is clearly using Applicant's specification as a roadmap to arrange the elements chosen from Muchin and this is clearly improper hindsight.

Independent Claims 1, 25, 30, and 39 recite that the second layer comprises one or more UVA and UVB radiation blocking agents. As discussed above, Muchin clearly teaches that only the first adhesive layer comprises one or more UV radiation blocking agents. There is no teaching that UV radiation blocking agents can be added to the pad layer of Muchin. In particular, it is submitted that Muchin does not disclose or suggest a patch as recited in Claim 1

which contains a second layer that comprises at least one UVB radiation blocking agent and at least one UVA radiation blocking agent. Muchin furthermore does not disclose nor suggest a method of making such a patch nor a method of reducing skin exposure to UV radiation comprising the use of such a patch as recited in Claim 25. In addition, there is no disclosure in Muchin to place the patch over an area of skin which is specifically susceptible to UV radiation as recited in Claim 30, e.g. over a mole or cluster of moles.

The Office Action previously asserted that Muchin taught the features of dependent Claim 37, namely that the patch of Muchin may contain UVA and UVB radiation blocking agents. The Office Action stated that “it would have been obvious to utilise any of UVA, UVB or UVC agents or a combination thereof based on the teaching of the addition of a UV agent to said formulations.” Applicant disagrees with the statements of the Office Action. Muchin does not provide any incentive to consider providing a combination of UVA and UVB agents. Thus, the Office Action is using hindsight to improperly reject the claims. As previously indicated, Muchin concerns a dermatological patch which is for removing keratotic plugs from the pores of skin to improve the health and appearance of skin. Thus, it is important to note that the entire concern of this Muchin is removal of keratotic plugs. This is clear from the background section of Muchin that keratotic plugs are dead epidermal cells combined with sebaceous matter and dirt which form within skin pores. The patch of Muchin is designed to be applied to the skin and then rapidly removed taking away keratotic plugs via a layer of adhesive which contacts the skin, as shown in FIG. 1. Thus, this patch of Muchin is not designed to be kept on the skin for a prolonged period of time. The only mention of UV absorbers in Muchin relates to generic UV absorbers in the adhesive layer as discussed above.

There is no suggestion or disclosure by Muchin to provide a patch for an application over a mole or area of skin which is particularly susceptible to UV radiation. Muchin fails to provide any guidance to consider UV absorbers in the context of providing a UV radiation barrier in the form of a patch. The Office Action can only rely on improper hindsight with which to alleged that the elements of the claims concerned with UV radiation agents are taught by Muchin.

There is certainly no disclosure or suggestion by Muchin to provide a combination of a UVA radiation blocking agent and a UVB radiation blocking agent. Furthermore, there is no suggestion that the patch has contained these agents in sufficient quantities so as to provide a UV protection factor of at least 15. Simply put, there is no reason why the skilled artisan would consider providing such a level of UPF to the Muchin patch because the patch in Muchin is not

intended to be kept on the skin; instead it is designed to be placed on the skin and immediately removed, taking the keratotic plugs with it. Therefore there is no requirement for a significant UV protection level to be provided by the patch.

The patch of the present invention provides an advantage since it prevents both UVA and UVB radiation, both of which are potentially harmful, from reaching an area susceptible to UV radiation. For at least these reasons, the patch and methods as claimed are novel and inventive over the prior art. Claim 1 is further distinguished by the introduction of the UV protection factor being at least 15. Again, it is not obvious to the skilled person to provide such a patch since there is no direction in the prior art to do so unless the technical problem solved by the present invention, namely that of preventing UV radiation to a mole, is considered first. To do so represents an impermissible use of hindsight.

Therefore, Muchin cannot render obvious Claims 1, 25, 30, and 39, and this rejection must be withdrawn.

2. Combination of Jenkins, Edwards and Woods Fails to Teach UVA and UVB radiation Blocking Agents.

Independent Claims 1, 25, and 30, as well as dependent Claims 2-5, 10-12, 18-20, 22, 23, 28 and 41-44 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of U.S. Patent No. 5,352,457 to Jenkins, et al. ("Jenkins") in view of U.S. Patent No. 6,037,280 to Edwards et al. ("Edwards"), WO02/059407 to Woods et al. ("Woods") and U.S. Patent No. 5,609,945 to von Trebra et al. ("von Trebra"). Applicant traverses this rejection in view of the arguments set forth below.

Independent Claim 1, as amended, also recited a patch comprising "one or more UVA (320-400 nm) radiation blocking agent and one or more UVB (280-320 nm) radiation blocking agents." As stated above, Claim 1 was amended to incorporate features of dependent Claim 37. Independent Claims 25 and 30 are also amended to recite similar features. None of the references, Jenkins, Edwards, Woods or von Trebra, were cited against Claim 37 and thus, each of these references either alone or in combination fails to teach every element Claims 1, 25, and 30. Thus, the rejection must be withdrawn.

E. Dependent Claims

Dependent Claims 2, 3, 33-36 and 38 stand rejected under 35 U.S.C. § 103(a) as being

unpatentable over Muchin in view of U.S. Publication No. 2003/0175328 to Shefer et al. (“Shefer”). Dependent Claims 10 and 26 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Muchin in view U.S. Patent No. 5,167,649 to Zook (“Zook”). Dependent Claim 32 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Muchin in view U.S. Patent No. 6,103,275 to Seitz et al (“Seitz”). Dependent Claim 32 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Muchin in view Edwards. Dependent Claims 16 and 17 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Jenkins, Edwards, Woods, and von Trebra, in further view of Muchin. Dependent Claims 21 and 26 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Jenkins, Edwards, Woods, and von Trebra, in further view of Zook.

Furthermore, combining Muchin with any of the other cited prior art fails to arrive at the present invention as recited in the claims. Shefer et al discloses a patch for controlled delivery of agents into the skin. Thus, Shefer is not concerned with a patch which contains UV blocking agents that are not intended to be delivered to the skin. Instead, the UV blocking agents are intended as a barrier to the skin. In addition, Shefer does not disclose a patch which comprises a second layer containing the UVA and UVB blocking agents. In addition, Shefer does not disclose that UV blocking agents may be present in the patch in such a quantity so as to provide a patch which has a UPF of at least 15, which is a recognised standard of protection.

Zook does not provide any of the features recited in the independent claims that are missing from Muchin or Shefer.

Similarly, Seitz does not complete the teachings of Muchin. Seitz is concerned with tissue healing and the use of nitric oxide. There is no disclosure of a patch comprising at least one UVA and at least one UVB radiation blocking agents nor that the patch provides a UPF of at least 15.

Edwards has been cited against the subject matter of “UPF of at least 15”. Edwards however is concerned with textiles having reduced UV transmission. The fabrics are for use e.g. as clothing or awnings.

Dependent Claims 2, 4, 5, 10-12, 17-23, 26, 28, 31-36, 38 and 42-45 depend from independent Claims 1, 25, 30 and 39, respectively. Accordingly, Claims 2, 4, 5, 10-12, 17-23, 26, 28, 31-36, 38 and 42-45 incorporate the features of independent Claims 1, 25, 30 and 39, and are patentable over the cited references for at least the same reasons as independent Claims 1, 25, 30 and 39.

F. Conclusion

In view of the above remarks, it is believed that this application is in condition for allowance, and a Notice thereof is respectfully requested.

Applicant's undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 625-3536. All correspondence should continue to be directed to the below-listed address.

Respectfully submitted,

/Keith DS Fredlake/

Attorney for Applicant

Keith Fredlake

Registration No. 58,006

Patent Administrator
KATTEN MUCHIN ROSENMAN LLP
2900 K Street, NW / Suite 200
Washington DC, 20007